K063234

NOV 2 1 2006

510(K) – SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	I-Flow Corporation 20202 Windrow Drive Lake Forest, CA. 962630
Contact:	Shane Noehre Director, Regulatory Affairs I-Flow Corporation
Trade Names:	ON-Q Introducer, ON-Q Needle, ON-Q Tunneler, ON-Q Sheath
Common Name:	Catheter Introducer Needle
Device Description:	The *ON-Q Introducers* consist of the following two components: • The first component is a stainless steel shaft (trocar) with a handle or luer hub. The trocar diameter ranges from 11 to 17 GA and the length ranges from 3.25 to 12 inches. The trocar may have a sharp, beveled tip or a blunt, rounded tip. • The second component is a peelable (split T-Handle) plastic sheath that is designed to fit over the trocar. The model configurations are designated as follows: • Models with a blunt tip are called ON-Q Tunnelers. The sheaths may be sold separately and are single use only. Some versions of the ON-Q Tunnelers may be reusable. • Models with a sharp tip are called ON-Q Introducers Needles which are single use only. The *ON-Q Introducers* are intended for the percutaneous introduction and placement of catheters into or around surgical wound sites and/or close proximity to nerves. Introducers with a luer hub may be used to aspirate or inject a bolus of fluid or medication prior to placing the catheters.
Standards:	The *ON-Q Introducers* meet the requirements of the following FDA recognized consensus standards for the device design and performance requirements: • ISO 10555-5:1996, Sterile, Single-Use Intravascular Catheters – Over Needle Peripheral Catheters • ISO 10555-1:1995, Sterile, Single-Use Intravascular Catheters – General Requirements • ISO 594-1:1986, Conical Fittings with 6% (Luer) Taper – Part 1 • ISO 594-2:1998, Conical Fittings with 6% (Luer) Taper – Part 2 • ISO 9626:1991, Stainless Steel Needle Tubing
Technology Comparison:	The *ON-Q Introducers* use the same technology as legally marketed predicate devices.
Conclusion:	The *ON-Q Introducers* are substantially equivalent to existing introducers that are currently marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

NOV 2 1 2006

Re: K063234
Trade/Device Name: On-Q Introducers
Regulation Number: 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: October 24, 2006
Received: October 25, 2006

Dear Mr. Noehre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

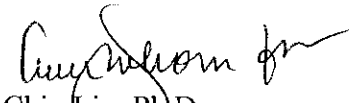
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063234

Device Name: ON-Q Introducers

Indications For Use:

1. The *ON-Q Introducers* are intended for the percutaneous introduction and placement of catheters into or around surgical wound sites and/or close proximity to nerves. Introducers with a luer hub may be used to aspirate or inject a bolus of fluid or medication prior to placing the catheters.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/21/2006

...of Anesthesiology, General Hospital,
...ion Control, Dental Devices

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